January 10, 2005

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2004D-0466

To Whom It May Concern:

The National Nutritional Foods Association ("NNFA") is submitting these comments to the Food and Drug Administration ("FDA") in response to the November 9, 2004 Notice, "Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act" ("Draft Guidance"), 69 Fed. Reg. 64962.

NNFA is a trade association representing the interests of more than 8,000 retailers, manufacturers, suppliers, and distributors of foods, dietary supplements, and other natural products throughout the United States. NNFA appreciates the opportunity to comment on the questions posed by FDA and commends FDA for its ongoing efforts to ensure the safety of the food supply.

FDA's initiative to further implement and enforce all provisions of the Dietary Supplement Health and Education Act of 1994 ("DSHEA") should be applauded. However, NNFA has some reservations regarding the approach FDA may take in its initiative to ensure that dietary supplement labels are truthful and not misleading. First, NNFA agrees with FDA's position that claims used in labeling should be substantiated by scientific evidence. However, NNFA believes that FDA's position – as outlined in the Draft Guidance – may be too narrow. Second, NNFA is concerned with FDA's expansion of labeling requirements not established by DSHEA.

I. FDA Should Not Restrict Relevant Studies to those that Match the Claim Being Made

In large part, FDA's Draft Guidance echoes the Federal Trade Commission's ("FTC") previously stated substantiation policy[1] in requiring "competent and reliable scientific evidence" for claims. However, FDA's Draft Guidance seems to go a step further and asserts that for studies to be deemed relevant for substantiation purposes, they must bear a precise relationship to the specific claim being made.

Toward this end, FDA takes the position that the endpoints of studies used to substantiate structure/function claims must *match* the claim being made. For example, studies supporting an "increased circulation to the brain" claim should have looked solely at increased circulation in the brain – and not at a broader disease state.

This position could potentially *limit* the body of evidence that dietary supplement companies can draw from in substantiating product claims. Many studies are funded and undertaken to research the effects of a substance on disease, rather than on a structure or function of the body alone. Qualified scientists are able to extrapolate information from such studies that support lesser claims or may give insight on other aspects of the supplement's function, such as the mechanism of action.

[1] "Dietary Supplements: An Advertising Guide for Industry," available at http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm.

Therefore, FDA should not categorically exclude such studies from forming the basis for structure/function claims. Rather, such studies should be permitted if scientists believe they, possibly together with other data, provide a foundation or some level of substantiation for a claim.

II. Foreign Studies

NNFA is also concerned about the restrictions the Draft Guidance places on the use of foreign studies in substantiating claims. In the Draft Guidance, FDA states that foreign studies may be used to substantiate claims as long as there are no significant differences between the study population and the U.S. population. FDA notes that confounding differences that would undermine the use of such studies include "differences in diets, general health, or patterns of use."

While NNFA understands FDA's point, the organization is concerned that this reasoning could be used to take an overly restrictive position against foreign-based studies used for claim substantiation on grounds of population type, environment or other factors. FDA is currently relying extensively on foreign studies under its Time and Extent Applications (21 C.F.R. §330.14) in the Over-the-Counter drug context. Given this fact, foreign studies should be able to form the basis of substantiation for dietary supplements if experts in the field could rely on them for such support.

III. FDA's Novel Requirement that Dietary Supplement Labels Must Bear "Material Facts" in Not Supported by DSHEA

In a related document issued on November 4, 2004, as part of FDA's Strategy for Dietary Supplements, FDA stated that it will take action against products whose labeling fails to reveal material facts. In this context, FDA stated that a dietary supplement is misbranded if its labeling lacks information (or includes misinformation) that is *material* in light of the claim made for the product or of the consequences that may result from using the products. According to FDA, situations in which a product can be misbranded for "omitting a material fact" include the failure to disclose known drug interactions, adverse effects or other information necessary for consumers to safely use the product or understand its labeling.

NNFA wants to take this opportunity to express concern about this position. DSHEA does not require dietary supplement labels to contain any warning information or information regarding drug interactions, although a company will do so on its own when necessary. FDA's move here, however, appears to implicitly require such statements by placing the burden on manufacturers and distributors to generate and then disclose such information. NNFA is unclear as to how to advise members do this, and what level and type of disclosure will satisfy the agency's new "requirement."

We also have concerns about potential product liability implications of this move, particularly in light of the wave of consumer protection cases appearing in state courts challenging companies for alleged labeling violations, including the failure to warn.

IV. Conclusion

NNFA appreciates the opportunity to comment on the Draft Guidance.

Respectfully submitted,

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